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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,789	09/12/2001	Charlie Ricci	018413-378	8809

38706 7590 04/05/2005

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EXAMINER	
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ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/05/2005

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/954,789
Filing Date: September 12, 2001
Appellant(s): RICCI ET AL.

Stephen Todd
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 22, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 16, 20-32 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,951,599	McCrory	9-1999
5,695,480	Evans et al	12-1997

- Chuter et al. "Endovascular Aneurysm Repair in High-Risk Patients" J Vasc. Surg vol 31 (January 2000), pp. 122-133.
- May et al. "Comparison of First- and Second- Generation Prostheses for Endoluminal Repair of Abdominal Aortic Aneurysms: A 6-year Study With Life Table Analysis" J Vasc Surg, Vol 32 (July 2000), pp. 124-129.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16, 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCrory in view of Chuter, May and Evans.

The instant claims are directed to kits comprising a fluid composition that forms a coherent mass in the presence of blood comprising a biocompatible solvent and a biocompatible polymer, a catheter suitable for delivering the fluid composition, a catheter suitable for delivering an endovascular prosthesis to the aneurysm, and an endovascular prosthesis comprising a stent-graft.

McCrory teaches occlusive systems including a stent for deployment in the parent vessel, a catheter for insertion of the device, a liquid polymeric embolizing composition to seal aneurysm sac and a microcatheter to deliver the embolizing composition (see abstract, col 3, lines 60-col 4, lines 24; col 5, lines 25-58; col 6, lines 15-60 and figures 6A-B; col 8, line50-col 9, line 20; col 12, lines 13-25). The stent of McCrory is an endovascular prosthesis. The composition of McCrory meets the element (a) of the instant claims because a liquid embolizing compositions comprises a biocompatible polymer and solvent. McCrory does not teach stent-grafts.

Chuter and May collectively teach that stent-grafts and stents are interchangeably used in the art to treat vascular aneurysm. Specifically, Chuter describes endovascular repair methodologies in patients using stent-grafts (abstract;

pages 126-130). May describes that both first generation prostheses, such as stents, and second-generation prostheses, such as stent-grafts, are effective in treating abdominal aortic aneurysm (see abstract, table III at page 127; pages 127-129).

Evans is merely used to show assembling a kit for vascular repair procedure comprising an embolic polymeric composition, which solidifies *in vivo*. Evans also teaches a prosthetic device such as a metal coil with different size catheters for delivering the composition and arresting the blood flow during the procedure (see abstract, col 4,lines 26-47; col 10, lines 31-41; col 11, lines 52-67; col 13, lines 1-43). Evens fails to teach the stent-graft in his kits.

However, it would have been *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, claims that require no more than mixing together of conventional elements used in the art for the same purpose set forth *prima facie* obvious subject matter. *In re Kerkhoven*, 205 USPQ 1069 (CCPA) 1980. In the instant case, all elements of the instant claims are taught in the art. Accordingly, it would have been obvious at the time of invention to add a stent-graft taught by Chutter and May to McCrory's system and assemble a kit to facilitate convenience during a vascular repair procedure as taught by Evens.

Moreover, as shown by Chutter and May Stent-grafts and Stents are art recognized equivalent in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute the stent of McCrory's

system with a stent-graft taught in May and form a surgical kit as shown by Evans, because the person of ordinary skill in the art would have had a reasonable expectation of success in achieving similar therapeutic results as described in McCrory.

Claims 16, 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans US Patent 5,702,361 in view of Chutter.

Evans teaches preparing kits comprising a polymeric embolic composition, a delivery catheter, and a catheter suitable for delivering an endovascular prosthesis. See abstract, col 4, lines 10-49. Evans also teaches the use of suitable contrast agents such as iopamidol, polymeric moieties, and solvents encompassed by the instant dependent claims. See col 7 lines 5-col 8, line 4; col 6, lines 27-35. See entire abstract, pages 123-125. Evans does not teach the use of stent-grafts.

Chutter teaches the use of stent-grafts for repairing treating post AAA repair. See entire abstract, pages 123-125.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the kit taught in Evans by adding a stent-graft or replacing the stent device of Evans with a stent-graft to facilitate ease and convenience during an aneurysm repair procedure. The ordinary would have been motivated to do such modification, because as shown by Chutter employing a stent-graft for treating AAA or an endoleak secondary to AAA surgery would have been safe and effective in patients at high risk and use of such device during a AAA repair is foreseeable.

(11) Response to Argument

Appellant's arguments have been fully considered but are not persuasive. Appellants argue that (I) neither Chuter nor May constitute prior art against the claimed invention and (II) the combination of the cited references does not produce the claimed invention because (A) neither Chuter nor May establish that stents and stent-grafts are interchangeable devices for endovascular repair and (B) one of skilled in the art would not be motivated to combine Chuter and/or May with McCrory.

In response, Examiner states that contrary to Appellant's position (I) Chuter and May are competent prior art because they are published before the effective filing date of the instant claims and (II) the combination of the cited reference produce the instantly claimed invention because (A) Chuter and May describe stent and stent-grafts to be interchangeable in the art of preparing surgical kits and (B) one of ordinary skill in the art would have been motivated to combine the cited references to reach the instant claims. Accordingly, for the reasons set forth below the Board of Appeals and Interferences (the Board) should uphold the rejections of record.

Please note that Appellant has not argued the individual rejections on the record. Accordingly, Examiner's response parallels the arguments presented by the Appellants.

I. The Board should maintain the rejections because contrary to Appellant's arguments Chuter and May were published before the effective filing date of the instant claims. Thus, they are competent prior art.

A. The effective priority date of the instant claims is the filing date of the instant application, which is March 20, 2000, because that is the earliest time that Appellant has envisioned the instantly claimed kits.

As it has been elaborated during the course of the prosecution of the pending claims, the Examiner has determined that the effective priority date of the instant claims is March 20, 2000 and not March 20, 1999, because March 20, 2000 is the earliest time that Appellants could have envisioned the use of stent-grafts in the pending claimed kits. (see footnote 2 in the Final Office Action filed on April 4, 2004 and the Advisory Action filed on August 17, 2004).

Appellant has argued that the instant application is a divisional of US Patent Application Serial No. 09/528,656, now US Patent 6,475,466, which, in turn, is a continuation-in-part of US Patent Application Serial No. 09/273,120,now US Patent 6,203,779. (see Brief at page 5, 1st para). Appellant adds that the '120 "grandparent" application has a filing date of March 19, 1999, which is prior to the publication date of both the cited Chuter and May references which were published in 2000. (see Id.).

In response Examiner states that in order to be entitled to an earlier priority date or filing date under 25 USC 120, each claim limitation must be expressly, implicitly or inherently supported in the originally filed disclosure. (see MPEP 2163.05). Even though claims as filed in the original specification are viewed to be a part of the disclosure (see MPEP 2163 I.B.), support for the claim limitations must meet the written description requirement of 35 USC 112, first paragraph. (see Id.). Under the written description requirement of 35 USC §112, first paragraph, the appellant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she *was in possession of the invention*.[1] (see MPEP 2163.05 (I)).

[1] Examiner has chosen to italicize and underline specific phrases in the MPEP or cited case laws for emphasis.

Although one might not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. In re Gosteli, 872 F.2d 1008, 1012,10 USPQ2d 1614, 1618 (Fed. Cir. 1989), also see MPEP 2163.02. Thus, the test for sufficiency of support in a parent application is whether the disclosure of the application relied upon, "reasonably conveys to the artisan that the inventor had possession *at that time of the later claimed subject matter*." Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). Here, such support is missing in the '120 grandparent application.

Consistent with the rule set forth above, the possession of the instantly claimed invention, as a whole, is assessed based on the combined features of the claimed kit including the placement of an endovascular prosthesis comprising a stent-graft inside the kit in combination with the recited fluid composition. The '120 "grandparent" application has failed to describe such combination or existence of a stent-graft in a kit. Therefore, the correct priority for the instant claims can not be earlier than the effective filing date of the parent case for this application which is March 20, 2000.

B. Contrary to Appellant's argument the reference to Parodi's article in '120 grandparent application does not satisfy the written description requirement under 112 first paragraph, because it does not clearly convey to one of ordinary skill in the art what the applicant was in possession at the time of filing.

Appellant argues that the priority of the claimed invention is March 1999, because all other aspects of the claimed invention were described in the '120 grandparent except the explicit recitation of "stent-graft." (see Brief at page 5, 2nd-3rd para.). Appellant then adds that the teachings in the specification allow the introduction of any endovascular prosthesis including those described in Parodi's article. (see Id.) Appellant finally asserts that Parodi describes the use of stent-grafts in treating abdominal aneurysms and all the teaching of Parodi is incorporated by reference in its entirety into the '120 grandparent application. (see Brief at page 6, 2nd para). Therefore, Appellant appears to conclude that the written description requirement is met because the '120 grandparent application contemplated the use of stent-grafts as an endovascular prosthesis. (see Brief at 3rd para.)

As the initial matter, Examiner failed to locate any reference in the '120 grandparent application with regard to incorporation of Parodi in its entirety into the grandparent application. Nevertheless, Examiner has addressed Appellant's arguments in the Advisory Action mailed on April 4, 2004. Accordingly, the question here is not whether a claimed invention is an obvious variant of that what is disclosed in the '120 grandparent specification. Rather, whether the '120 prior application itself described the claimed kits, and had done so in sufficient detail that one skilled in the art can clearly conclude that the appellant invented the claimed invention as of the filling date sought.

In response to Appellant's arguments Examiner repeats the same reasoning as provided in the Advisory Action. The written description standard of 35 USC 112 first paragraph requires a clear description of what does one have "in possession" at the

time of invention, not what which makes it obvious. see Lockwood v. American Airlines Inc., 107 F3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir, 1997). In order to gain the benefit of the filing date of an earlier application under 35 U.S.C. 120, each application in the chain leading back to the earlier application must comply with the written description requirement of 36 U.S.C. 1 112. In re Hogan, 559 F.2d 595, 609, 194 U.S.P.Q. (BNA) 527, 540 (CCPA 1977).

Entitlement to a filing date does not extend to subject matter, *which is not disclosed, or would be obvious over what is expressly disclosed. It extends only to that which is disclosed*. While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art all the limitations must appear in the specification. *The question is not whether a claimed invention is an obvious variant of that what is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the in inventor invented the claimed invention as of the filing date sought*. See Madin v. Mayer, 823 F.2d 500, 504, 3 U.S.P.Q.ZD (BNA) 1333, 1337 (Fed. Cir. 1987) quoting Jepson v. Coleman, 50 C.C.P.A. 1051, 314 F.2d 533, 536, 136 U.S.P.Q. (BNA) 647, 649-50 (CCPA 1963)). One shows that one is "in possession" of the invention by describing the invention, *with all its claimed limitations, not that which makes it obvious*. Id.

Here, Appellant appears to argue that preparing a kit containing the stent-grafts described in Parodi would have been obvious to one of ordinary skill in the art who reads the grandparent application. However, following the reasoning in Lockwood, what

would have been obvious, is not the standard for satisfying the written description requirement. *The standard is a clear description of what is in possession of the inventor at the time of filing*. Examiner states that the reference to Parodi in the '120 grandparent application, is in passing to describe what is the state of art for treating aneurysm, not what is in possession of the inventor at the time of invention. Accordingly, Appellant's arguments should not be found persuasive.

Furthermore, to overcome the rejections of record, Appellant throughout the prosecution of this Application, has argued that Stent-grafts are actually different from other prosthesis in the art taught by Evans, or that stent-grafts are not art equivalent to other types of prior art stents for preparing surgical kits. (see Amendment filed on January 22, 2003 and the Declaration filed by Dr. Greff filed on January 22, 2003). However, such reliance on the Parodi and its teachings appears to undermine Appellant's own arguments to overcome the prior art rejection of record, because it goes to show that one of ordinary skill in the art would have understood that any endovascular prosthesis, i.e. regular stents or stent-grafts of Parodi, could have been placed in the surgical kit described in McCrory or Evans. For such reasons alone, the board should affirm the rejection.

C. Contrary to Appellant's argument the use of Wallgraft™ in Example 2 of '120 grandparent application does not satisfy the written description requirement of 112 first paragraph, because such use of the Wallgraft in Example 2, is in direct opposition of the proposed use of the instantly claimed kits.

Appellant argues that Example 2 of the '120 application describes the use of Wallgraft which is a stent-graft. (see Brief at page 6, 3rd para.). Accordingly, Appellant

concludes that '120 application clearly contemplates the use of stent-graft as an endovascular prosthesis. (see Id. at 4th para.).

In response, Examiner states that a fair reading of the example 2 in '120 grandparent application, as a whole, suggest the use of perforated Wallgraft as a model for a graft defect and/or a source of endoleak. Examiner failed to locate any suggestion in the '120 grandparent application where Wallgraft is used for the proposed use of the instantly claimed kits which is for "sealing the endoleaks arising from endovascular repair." Such use of Wallgraft in example 2 of '120 application appears to be a direct teaching away from the proposed use of the claimed kit and the prosthesis contained therein. Examiner did not view the use of Wallgraft in '120 grandparent application as a clear description or conveyance to those of skilled in the art, that Appellants were in possession of such kits with stent-grafts at the time filing of the '120 application. Therefore, such line of argument was not found to be persuasive.

In conclusion, the Board should recognize that Appellant argues that it would have been obvious to use stent-grafts in the kits disclosed in the '120 grandparent application. However, such line of reasoning does not meet the written description standard of 35 USC 112 first paragraph. Thus, the Board should affirm recognize Chutter and May as competent prior art because the priority of this application is March 20, 2000.

II. The combination of the cited reference produces the claimed invention because (A) it teaches all elements of the instant claims, and (B) one of ordinary skill in the art would have been motivated to combine Chuter and/or May with McCrory or Evans to reach the instant claims.

A. Contrary to Appellant's arguments the combined references meet all the limitations of the instant claims and further establish that the stents and stent-grafts are interchangeable in the art of preparing surgical kits.

Appellant argues that neither of Chuter or May would establish that stents and stent-grafts are equivalent devices for endovascular repair (see Brief at page 7, 3rd para.). In response, Examiner states that the issue here is not whether stents and stent-grafts are art recognized equivalents for endovascular repair. Rather, whether they are art recognize equivalents *for the purposes of assembling a kit* containing components that are used during a endovascular surgery. Accordingly, Examiner does not find Appellant's arguments persuasive.

Throughout the prosecution, Appellant has argued that stent-grafts are not synonymous or equivalent to stents of McCrory or Evans because a surgeon would not use one in place of another or that such devices function differently (see Appellant's Arguments filed January 22, 2003 at page 3-4 and the Declaration filed by Dr. Greff filed on January 22, 2003). In reply the Examiner states that the rejection of record does not require modification of the stent, how it is being used or how it should function, rather the rejection sets forth whether it would have been obvious to one of ordinary skill in the art to assemble the components of the instantly claimed kits.

Here, Appellant appears to ignore the 3rd criteria described in *Graham* v. *John Deere Co.*, for establishing an obviousness rejection under 35 U.S.C. 103(a). The third criteria set forth in *Graham* requires the Examiner to resolve the level of ordinary skill in the pertinent art. As Examiner clarified his position in the Advisory Action filed on June 5, 2003 and the subsequent Actions, the level of ordinary skill in the art of preparing

surgical kits does not require the expertise of a heart surgeon, rather one who *assembles kits for surgical convenience and ease of access to surgical components* including nurses, surgical technicians and other competent hospital staff. Accordingly, the rejection is not based on the interchangeability of stent and stent-grafts during the actual an endovascular aneurysm repair procedure. Rather, the interchangeability of stent and stent-graft for the purposes of *preparing convenient kits for use* in an endovascular repair procedure.

Having such level of ordinary skill in the art in mind, the Examiner maintained the rejection because both Chuter and May suggest that stents and stent-grafts are both readily used for treating endovascular injuries. Therefore, it would have been obvious to add them both to a surgical kit. This reasoning does not rely on interchangeability of stents and stent-grafts. Rather, a mere addition of stent-graft to kits containing stents for ease of access during a surgical procedure.

In fact, the rejection of record first relies on the reasoning set forth *In re Kerkhoven.* Accordingly, Examiner took the position that under the competent rules of Patent Law, it would have been foreseeable to one of ordinary skill *in the art of assembling surgical kits* to add the stent-grafts of May or Chutter to surgical kits suggested in McCrory and Evans and further facilitate convenience and ease of access to all necessary surgical components during a vascular surgical procedure.

Only after setting forth such reasoning, the Examiner employed an alternative approach for rendering the instant claims obvious by describing that it would have been obvious to one of ordinary skill in the art at the time of invention to replace the stents of

McCrory or Evans with stent-grafts described by May or Chutter. Accordingly, for such reasons, the rejection should be maintained.

B. One skilled in the art would be motivated to combine the teachings of the cited references.

Appellant argues that the cited references do not provide any suggestion or motivation to combine the references because there exist no expectation of success. (see Brief at pages 8-9).

In response, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Chutter and May provide a general knowledge in the art about how to use stent-grafts and stents for treating endovascular repair. Further, both McCrory and Evans provide ample motivation and suggestion to combine an embolic composition and suitable endovascular prosthesis for purposes of preparing a kit for surgical procedure. Therefore, there is ample suggestion available to one of ordinary skill in the art to prepare convenient kits prior to a complex surgical procedure. Since all cited references are within the same filed of endeavor and attempt to resolve the same problem in the art, they are viewed to be combinable.

Finally, Examiner points out that the pending claims are directed to kits comprising a stent-graft, a catheter and a polymeric composition, not a method of performing a surgical procedure. McCrory uses a stent instead of a stent-graft in preparing his kits. However, the secondary references in the instant rejections elaborate that in the art of assembling kits for surgical convenience, stents and stent-grafts are viewed to be art equivalents. Therefore, substituting stent-graft in place of a stent in the kit of McCrory and Evans would have been obvious. Accordingly, the rejection should be maintained.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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